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UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

DONOR NETWORK WEST,

Plaintiff,

v.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services,

STEPHANIE CARLTON, in her official capacity as Acting Administrator of the Centers for Medicare & Medicaid Services,

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

CENTERS FOR MEDICARE & MEDICAID SERVICES,

Defendants.

Case No. _____

COMPLAINT

Plaintiff Donor Network West ("DNWest") brings this Complaint against defendants the United States Department of Health and Human Services, the Centers for Medicare & Medicaid Services, Robert F. Kennedy, Jr., in his official capacity as Secretary of HHS, and Stephanie Carlton, in her official capacity as Acting Administrator of CMS (collectively, "CMS"). In support, DNWest alleges as follows:

NATURE OF THE ACTION

1. This litigation requests that the Court enforce the requirements of both the National Organ Transplant Act and the Administrative Procedure Act by declaring unlawful and vacating CMS's final decision issued on December 19, 2024, which is attached to this complaint as Exhibit 1. That decision permits a hospital within DNWest's exclusive and federally designated service area to terminate its contract with DNWest and to work instead with another organ procurement organization (Nevada Donor Network), despite DNWest's long and successful relationship with the hospital. In issuing its decision, CMS did not comply with the statutory requirements, which clearly set forth the criteria that CMS must apply before permitting a hospital to abandon its designated organ procurement organization. Nor did it respond to serious allegations that Nevada Donor Network has engaged in misconduct, including evidence in the administrative record showing that Nevada Donor Network unethically offered the hospital a multi-million-dollar payoff on the condition that it abandon DNWest. CMS's decision violates the statute, is unreasonable, and is not supported by any reasoned explanation. The Court's intervention is urgently required to prevent substantial and irreparable harm not only to DNWest but also to the organ donor families within its designated service area, to the potential organ recipients waiting on the national transplant list, and to the overall integrity of the nation's organ donor system.

2. DNWest is a non-profit, federally designated organ procurement organization committed to saving and healing lives through facilitating organ and tissue donation. DNWest works closely with acute care hospitals and donor families to identify and assess potential organ donors, and then to ensure that the organs it recovers are preserved and delivered to patients in need of a life-saving transplant. Offering a strong network of support, DNWest works diligently to educate hospital staff, community partners, and donor families on the organ referral and donation process.

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DNWest is one of 55 non-profit organ procurement organizations across the United States that are certified by CMS to operate within specified "donation service areas."

3. To develop an efficient, robust, and equitable organ donation and transplant system, Congress enacted the National Organ Transplant Act, which establishes a network of donation service areas across the country that are each served exclusively by a government-certified organ procurement organization. The statute requires that each organ procurement organization and each donor hospital in that organization's donation service area enter into an exclusive agreement to work together to maximize organ donation and retrieval. The system relies on building strong relationships and stable lines of communication between each organ procurement organization and the donor hospitals in their designated service areas. The statutory requirements and safeguards are designed to enhance and increase successful organ donation and recovery for those who anxiously await a life-saving organ transplant.

4. For more than forty years, DNWest has served as the federally designated organ procurement organization for the donation service area consisting of geographically interconnected counties in northern Nevada and northern California. In that role, DNWest has long successfully partnered with Renown Health and its various hospitals, including Renown Regional Medical Center ("Renown"), a large donor hospital located in Reno, Nevada.

5. DNWest's partnership with Renown has been extraordinarily successful and has helped Renown become one of the most successful donor hospitals in the country. In fact, the positive relationship over the years has caused the hospital's organ donation volumes to be in the top one percent of all donor hospitals nationwide. DNWest has invested heavily in its relationship with Renown, including staffing three full-time coordinators who perform daily rounds within the hospital, and leading many strategic quality-control and outreach programs at the hospital. DNWest has also made countless long-term infrastructure and other investments and partnerships in the Reno, Nevada community, and throughout the Nevada counties it serves, to educate the public and encourage organ donation.

6. The forty-year partnership between DNWest and Renown, and the stability of the organ donor system as a whole, is now in jeopardy because of unlawful and unreasoned actions taken

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by CMS. In particular, CMS has granted a "waiver" that improperly permits a different organ procurement organization—Nevada Donor Network—to displace DNWest and to take over the relationship with Renown despite CMS failing to make any of the statutory determinations that are required before a waiver may be granted. If CMS's unlawful decision is not corrected, DNWest and the many donor families that rely on it will be substantially and irreparably harmed.

7. Because of the importance of the exclusive donor service area system to the nation's organ donation system, Congress has strictly limited the circumstances under which CMS is authorized to grant waivers that allow hospitals within a designated service area to change the organ procurement organization to which they are assigned. Most importantly, CMS may not grant a waiver unless the agency first makes specific findings establishing that permitting the hospital to change organizations is (1) "expected to increase organ donations" and (2) "will ensure equitable treatment of patients listed for transplants within the service area served by the hospital's designated [organ procurement organization] and within the service area served by the [organ procurement organization] with which the hospital seeks to enter into an agreement" under the waiver. 42 C.F.R. § 486.308(e); *see also* 42 U.S.C. § 1320b-8(a)(2)(A).

8. Seeking to accomplish its publicly stated goal of displacing DNWest and becoming the only organ procurement organization in Nevada, Nevada Donor Network offered Renown $6 million dollars in federal funding upfront, and promised to secure an additional $9 million in further funding, toward the creation of a new transplant center at Renown. It then conditioned its offer on an astonishing requirement—Renown would be required to seek a waiver from CMS to abandon DNWest and shift to Nevada Donor Network, even though Nevada Donor Network is located outside the donation service area in which Renown is located. It is important to note that all organ procurement organizations work closely with a number of transplant centers and, as a result, establishing a new transplant center does not logically dictate any practical efficiencies that could justify changing an effective relationship with an existing organ procurement organization. Nonetheless, faced with such an enormous financial payoff, Renown requested that CMS grant a waiver to allow Renown to terminate its successful relationship with DNWest and to work instead with Nevada Donor Network.

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9. Nevada Donor Network's predatory conduct—and the obvious problems raised by its promised payoff—should have prompted CMS to comply with its statutory obligations and respond carefully to the many objections raised regarding this unseemly arrangement. Federal law does not allow a donor hospital to sell or accept remuneration for its statutorily prescribed partnership with its host organ procurement organization. But CMS failed to make the statutorily required determinations or to respond to the many objections raised by DNWest and other interested parties. No salient or quantifiable record evidence establishes that allowing Nevada Donor Network to pay for a switch in organ procurement organizations would lead to more organ transplants, more saved lives, or an increase of equitable treatment of patients.

10. CMS instead concluded that the waiver was justified based solely on an interim 2023 performance report (based on 2021 data) that provided interim tier ratings for organ procurement organizations. That interim rating was designed only to help organ procurement organizations monitor their progress as part of the 2026 recertification cycle. The interim 2023 performance report (based on 2021 data) cannot, and was never intended to, serve as a proxy for the statutory requirements for granting a waiver. To the contrary, as the statute makes plain, waiver requests must be evaluated based on a specific hospital's relationship with its designated organ procurement organization, and the decision whether to grant a waiver requires analyzing the consequences of permitting that hospital to change organizations. In contrast, the tiered ranking system is based on aggregated data throughout a donation service area and is not intended to assess whether a waiver would increase donations and lead to more equitable treatment for patients at a specific hospital. Moreover, the interim tiering reports have shown high variability from year to year and are not intended to take into account the nature of a long-standing relationship between an organ procurement organization and a specific hospital within its designated service area. The record evidence shows that DNWest's partnership at Renown has been exceptionally successful in increasing donor rates, keeping the costs of recovery low, and serving donor families for the past forty years. And to the extent any broader data could be relevant, Nevada Donor Network's performance metrics pale in comparison to DNWest's performance metrics at its Nevada hospitals.

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11. CMS also failed to consider or respond to important comments or to apply the statutory requirements faithfully. Most alarmingly, CMS failed to consider the equitable implications of Nevada Donor Network's offer of millions of dollars in funding to prompt Renown to seek a change in organ procurement organizations. Instead, while CMS accepted at face value Renown's assertion that its relationship with DNWest was harmed because DNWest had sued Nevada Donor Network, CMS failed to consider or even mention the underlying allegations in that lawsuit, which is predicated on Nevada Donor Network's tortious interference in the relationship between DNWest and Renown. Despite the litigation, the working relationship between DNWest and Renown has continued, and remains positive and effective as demonstrated by the numbers and staff interaction. Nonetheless, in a perverse twist, CMS assumed without evidence that the litigation would negatively impact DNWest's relationship with Renown and failed to address the egregious misconduct by Nevada Donor Network that prompted the litigation. CMS's unreasoned decision is arbitrary and capricious and falls far short of satisfying the requirements of reasoned decision-making mandated by the Administrative Procedure Act.

12. The Court's intervention is urgently required to avoid imminent and irreparable harm to DNWest and the patients it serves. Once the unlawful waiver takes effect in April, DNWest will be forced to stop providing service to Renown, disrupting the relationships, strategic programs, and operations that DNWest has spent four decades developing. If allowed to take effect, the waiver will have repercussions beyond Renown, as DNWest will suffer widespread reputational harm and may have to reduce the services it provides throughout its service area, which could jeopardize its operations at other facilities. It will also undermine the entire organ system, which depends on CMS faithfully applying the statutory requirements and preventing organizations (like Nevada Donor Network) from gaming the system by identifying and trying to buy off high performing organ transplant hospitals from outside their designated service area.

PARTIES

13. Plaintiff DNWest is a non-profit 501(c)(3) charitable organization formed under the laws of California with its registered office address at 12667 Alcosta Boulevard, Suite 500, San

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Ramon, CA 94583. DNWest is also a registered non-profit corporation in Nevada and maintains an office at 5440 Reno Corporate Drive, Reno, NV 89511.

14. DNWest is the nation's third largest organ procurement organization serving more than thirteen million people. DNWest connects organ, eye, and tissue donors to transplant recipients in forty-five counties geographically interconnected throughout Northern Nevada and Northern California, and on the national transplant wait list.

15. CMS designated DNWest to be the organ procurement organization for the designated service area for Northern Nevada. Pursuant to contracts with Nevada hospitals authorized by CMS and subject to Nevada law, DNWest serves the hospitals in the Nevada counties of Washoe, Carson City, Douglas, Mineral, Churchill, and Humboldt. *See* 42 U.S.C. § 273(a)–(b)(1), (3).

16. Defendant Department of Health & Human Services ("HHS") is an executive department in the United States government headquartered at 200 Independence Avenue SW, Washington, DC 20201.

17. Defendant Centers for Medicare & Medicaid Services is a component of HHS with responsibility for day-to-day operation and administration of the Medicare program and is located at 7500 Security Boulevard, Baltimore, Maryland 21244. The agency sets forth Medicare conditions of participation in the Medicare program for transplant programs and donor hospitals as well as outcome measure requirements and conditions for Medicare certification of organ procurement organizations.

18. Defendant Robert F. Kennedy, Jr., sued in his official capacity only, is the Secretary of HHS. The Secretary has ultimate responsibility for the administration of the Medicare program. His official address is 200 Independence Avenue SW, Washington, DC 20201. The Secretary has delegated to CMS his authority to make waiver decisions. References to the "Secretary" in this complaint are meant to refer to him, his subordinate agencies and officials, and to his official predecessors or successors as the context requires.

19. Defendant Stephanie Carlton, sued in her official capacity only, is the Acting Administrator of CMS. The CMS Administrator is responsible for administering the Medicare program. Her official address is 7500 Security Boulevard, Baltimore, MD 21244.

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JURISDICTION AND VENUE

20. This Court has jurisdiction under 28 U.S.C. § 1331 because this action arises under the laws of the United States.

21. Plaintiffs have a right to bring this action pursuant to the Administrative Procedure Act and the Declaratory Judgment Act. *See* 5 U.S.C. §§ 701–706, 28 U.S.C. § 2201.

22. Venue is proper in this district under 28 U.S.C. § 1391(e)(1) because a substantial part of the events or omissions giving rise to the claim occurred in this judicial district. CMS certified DNWest as the exclusive organ procurement organization to serve Northern Nevada and its waiver decision allows for a modification of terms in the contract it authorized between DNWest and a Nevada hospital that sets forth the terms of that exclusive service.

GENERAL ALLEGATIONS

A. The Statutory and Regulatory Framework

23. In 1984, Congress enacted the National Organ Transplant Act to establish a national system for overseeing organ donation and transplants. *See* Pub. L. No. 98-507, 98 Stat. 2339 (1984) (codified as amended at 42 U.S.C. § 273 *et seq.*). The statute establishes the Organ Procurement and Transplantation Network, a public-private partnership that links all entities and professionals involved in the U.S. donation and transplantation system.

1. The Designated Service Area System

24. Pursuant to the statute, CMS registers qualified organ procurement organizations and assigns each of these non-profit organizations' sole responsibility for an exclusive geographic area. The assigned area, which spans multiple counties and includes one or more transplant centers and one or more donor hospitals, is referred to as a designated "donation service area." 42 U.S.C. § 273(a), (b)(1)(E); *see also* 42 C.F.R. § 486.308(a) ("CMS designates only one [organ procurement organization] per service area."). Within that area, the assigned organization is required to transport, preserve, equitably allocate, and distribute donated organs that it recovers from donor hospitals. 42 U.S.C. § 273(b)(3)(A)–(K).

25. Designated service areas often transcend geographic and political boundaries. They are designed to be of "sufficient size" to "assure maximum effectiveness in the procurement and

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equitable distribution of organs." 42 U.S.C. § 273(b)(1)(E). Many states are served by two or more organ procurement organizations, and several organizations are responsible for service areas that extend across state lines.

26. To ensure effective coverage of each donation service area, federal law requires that every organ procurement organization enter into agreements with the substantial majority of the hospitals within its donation service area that have organ donation facilities or programs. 42 U.S.C. § 273(b)(3)(B).

27. Federal law also requires that donor hospitals work exclusively with the organ procurement organization assigned to the relevant donation service area. More specifically, the Social Security Act of 1935 requires all Medicare and Medicaid participating hospitals that conduct organ recovery or transplantation to have an exclusive agreement—referred to as "Affiliation Agreements"—with the organ procurement organization assigned to the geographic service area in which the hospital is located. 42 U.S.C. § 1320b-8(a)(1)(C).

28. This federally mandated regime of exclusive and defined service areas has been in place for decades and reflects Congress's judgment that maintaining designated service areas is critical to the national infrastructure for organ donation. There are several well-recognized benefits of this system.

29. First, because organ procurement organizations must have agreements in place with a "substantial majority" of donor hospitals in each of their donation service areas, the system ensures that the organizations provide support and coverage *throughout* their service areas instead of cherry-picking hospitals with the highest donation rates. 42 U.S.C. § 273(b)(3)(A). The system thus helps to ensure that smaller or more rural hospitals and populations are properly and adequately served.

30. Second, the system prevents on-site competition at hospitals between organ procurement organizations, which could hurt community relations and make the donation process more difficult for a deceased donor's family. Building public trust is critical to an effective donation process and system. Having mixed messages conveyed to the families of loved ones who have just passed away by organizations competing to recover the loved one's organs would be extremely disruptive, potentially leading to fewer organ recoveries.

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31. Third, exclusive service areas help to ensure that fees charged by organ procurement organizations are tied to the actual costs of providing donor-focused services rather than have those costs inflated by unseemly marketing or business development activities.

32. Fourth, the donor service areas system helps to build longstanding, close, and beneficial partnerships between individual organ procurement organizations and the donor hospitals in its donation service area. Those partnerships ensure the existence of strong and stable relationships necessary for an efficient organ donation system and promotes broader community engagement and trust in organ donation.

2. The Certification Process

33. To ensure that a donation service area is properly served, organ procurement organizations are subject to a CMS certification process for their designated service areas every four years. 42 C.F.R. § 486.308(b). Following each four-year certification period, an organ procurement organization is either recertified for another four years or, in appropriate circumstances, subject to potential competitive bidding and decertification. *Id*. § 486.316(b).

34. Starting in 2026, the certification process will involve applying a controversial tiered-evaluation system. In December 2020, CMS promulgated a final rule to establish a new data collection and performance evaluation system for the nation's organ procurement organizations. *See* Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations, Final Rule, 85 Fed. Reg. 77,898 (Dec. 2, 2020). For the next certification cycle in 2026, CMS will use each organ procurement organization's 2024 donation rate and transplant rate for its donation service area and compare those rates on a nationwide basis to determine whether the particular organization should be designated as Tier 1, Tier 2, or Tier 3. 42 C.F.R. § 486.316. In the meantime, each year from 2021 through 2023, CMS has published a performance report (based on data from two years prior) to monitor organ procurement organizations' progress. These interim reports will not be used to determine the final tier status for the 2026 certification cycle—only the 2026 report (based on 2024 data) will be used for this purpose. Moreover, these reports have shown that the interim data is highly variable, with major shifts happening each year in the number of organizations that qualify

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(on an interim basis) as Tier 1, Tier 2, or Tier 3. *See, e.g.*, CMS, Organ Procurement Organizations, Annual Public Aggregated Performance Report (2023), https://tinyurl.com/2k4bywvp.

35. In 2026, Tier 1 organizations will be recertified for their donation service areas for an additional four years. *See* 42 C.F.R. § 486.316(a). Tier 2 organizations will not be automatically recertified but will have to compete to retain their donation service areas. *Id.* Tier 3 organizations will be decertified and precluded from competing for open donation service areas. *Id.*

36. If an organization serving a donation service area is not automatically recertified as Tier 1, the organization's donation service area becomes open to competition from other interested and eligible organizations. 42 C.F.R. § 486.308(a); 42 C.F.R. § 486.316(a)(2), (c).

37. Interested organ procurement organizations must compete for the "entire donation service area," not for individual hospitals or select geographic areas within the [donation service area]. 42 C.F.R. § 486.316(c).

38. This longstanding requirement pre-dates CMS's new tiering system and continues following its implementation. As CMS has explained, the requirement is necessary to "prevent competition of partial service areas, which may lead to [organ procurement organizations] attempting to obtain certain neighboring service areas purely for business reasons, with no regard to whether the [organization] can increase organ donation in those areas." 84 Fed. Reg. 70,628, 70,637 (Dec. 23, 2019).

39. Providing detail on the incentives the statute and regulations seek to avoid, CMS has explained its concerns that organ procurement organizations will engage in improper and predatory behavior. In particular, CMS has expressed concerns that out-of-area organizations will target hospitals with high donation potential without having to take on responsibility for meeting the demands of the entire designated service area.

> We have found that permitting competition for partial services areas provides an incentive for OPOs to attempt to "raid" portions of neighboring service areas for purely business reasons, with no regard to whether the OPO can increase organ donation in those areas. For example, an OPO may wish to take over counties in a neighboring service area where hospitals demonstrate high conversion rates, which would improve the competing OPO's overall outcome performance measures but lead to no actual increase in organ donation. An OPO with a tissue bank may want a section of another OPO's service area that has particularly high tissue donation potential in

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> hopes of expanding its tissue bank into the area. Because of the problems created by allowing competition for partial service areas, we believe it is critically important to require OPOs to compete for entire service areas.

70 Fed. Reg. 6086, 6094 (Feb. 4, 2005).

40. Under CMS regulations, competing for an "entire service area" is supposed to be a rigorous and transparent process. Multiple eligible organ procurement organizations are compared, and one is selected to be the new organ procurement organization permitted to serve the designated donation service area. 42 C.F.R. § 486.316(d).

3. The Waiver Process

41. The statute includes a "waiver" provision that permits CMS (exercising authority delegated by the Secretary) to grant, in limited circumstances and upon making specific determinations, a request by a donor hospital to work with a different organ procurement organization outside its assigned donation service area.

42. Because of the dangers they pose to the entire donor system, waivers are available only under limited circumstances. CMS is authorized to grant a waiver request only if the waiver meets two statutory requirements: the hospital must submit data to CMS establishing that the waiver is (1) "expected to increase organ donation" and (2) "will assure equitable treatment of patients referred for transplants within the service area served by such hospital's designated organ procurement agency and within the service area served by the organ procurement agency with which the hospital seeks to enter into an agreement under the waiver." 42 U.S.C. § 1320b-8(a)(2)(A); *see also* 42 CFR § 486.308(e).

43. As part of his review of the waiver request, CMS is expected (but not required) to consider certain other factors, including cost effectiveness, quality improvements, and "the length and continuity of a hospital's relationship with an organ procurement [organization] other than the hospital's designated organ procurement [organization]." 42 U.S.C. § 1320b-8(a)(2)(B); *accord* 42 CFR § 486.308(e).

44. Waiver approvals have traditionally occurred in circumstances where an organ procurement organization has a proven poor record of performance with a specific hospital and that

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hospital seeks a waiver to work with another organization to increase its donation rate. That occurred years ago when hospitals in several counties that used to be in Nevada Donor Network's service area applied for waivers to work with DNWest. DNWest never requested those hospitals to seek waivers nor enticed them to do so through financial incentives. The hospitals did so of their own accord to improve organ donation at their facilities, after Nevada Donor Network became the first and only organ procurement organization to be declared "A Member Not in Good Standing" by Organ Network in 2011 due to "concerns regarding quality and staffing practices." Exhibit 2 at 3 (capitalization altered). Because CMS granted those waivers, DNWest was asked to serve hospitals in the Nevada counties of Douglas, Mineral, Churchill, and Humboldt. Exhibit 3 at 6–7.

45. Although the Social Security Act is "quite specific in detailing the process for the waiver requests," 86 Fed. Reg. 19,722, 19,740 (May 2, 1996), CMS has failed to implement a "specific … process" to analyze those requests. To the contrary, CMS staff has conceded that CMS "do[es] not have the resources nor the expertise to perform the analyses necessary to determine whether an [organ procurement organization's] waiver request should be granted or denied." Exhibit 4 at 3 (February 15, 2024 email from CMS to HRSA); *see also* Letter from H. Comm. on Oversight & Accountability, 118th Cong., to Xavier Becerra, Secretary, HHS, at 3 (July 25, 2024), https://tinyurl.com/2d3hknud (noting that "disputes and uncertainties" related to waivers, including the dispute between DNWest and Nevada Donor Network, "could seemingly have been avoided by appropriate agency oversight and guidance.").

B. Donor Network West Has Successfully Served Its Donation Service Area, Including Renown, for More Than Forty Years

46. DNWest has been the sole organ procurement organization serving the donation service area of northern Nevada and northern California for more than forty years—even before Congress enacted the National Organ Transplant Act and established exclusive donation service areas. Exhibit 3 at 2.

47. DNWest is the federally designated organization responsible for serving the northern Nevada donation service area, which means that it is responsible for serving the following counties in Nevada: Washoe, Carson City, Douglas, Mineral, Churchill, and Humboldt. *Id.* at 7.

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48. The County of Washoe, where Renown is located, and the County of Carson City were originally designated to the donation service area DNWest serves. DNWest later took over responsibility for serving the counties of Douglas, Mineral, Churchill, and Humboldt after the hospitals in those counties sought, and were granted, waivers from CMS to work with DNWest after their then-existing organ procurement organization—Nevada Donor West—had documented performance issues.

49. DNWest serves 43% of the counties in Nevada that have a donor hospital. *Id.*

50. In the past five years, DNWest increased organ donations overall in its service area by 29% and, in 2022, DNWest had the highest donation rate of any organ procurement organization operating in Nevada. *Id.* at 3.

51. In 2019, DNWest was the first organization in the nation to increase organ donors in its service area by 92 organ donors in a single year—an accomplishment that was recognized by numerous government officials and agencies. *Id.* at 3.

52. As recently as May 9, 2022, DNWest was recertified as the designated organ procurement organization for the northern Nevada donation service area. CMS's 2022 recertification survey of DNWest, covering the period 2018-2021, found DNWest compliant with all Medicare requirements and identified zero deficiencies. Upon information and belief, DNWest was the only organ procurement organization in the country to achieve zero deficiencies during the 2018-2021 CMS recertification cycle.

53. DNWest's relationship with Renown's flagship hospital dates back to 1987 and has been an undisputed success story. Through their partnership, DNWest has recovered 678 organ donations at Renown since 1987, placing Renown in the top 1% of donor hospitals nationwide in total volume. In fact, the number of donors recovered from Renown places it 28th out of 2,570 recovery hospitals in the nation. *Id.* at 7.

54. In the last five years, DNWest has helped Renown increase and sustain a 46% increase over its already impressive donation rate in earlier years. *Id.* Moreover, Renown has consistently optimized donation metrics while partnering with DNWest, including referral rates, timeliness, and effective request processes. *Id.* at 23.

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55. DNWest has served two other smaller provider locations Renown operates in Reno, including (a) South Meadows Medical Center d/b/a Renown Rehabilitation Hospital and (b) Renown South Meadows Medical Center. DNWest's Affiliation Agreement covers all three facilities. The agreement is governed by Nevada law in accordance with applicable federal requirements.

56. Because of its longstanding commitment to the Renown facilities and to the Reno, Nevada area, DNWest has made long-term community investments that have contributed to Renown's success. For instance, DNWest operates a recently expanded 17,000 square foot Nevada facility headquartered in Reno that employs approximately 45 experienced staff members who work and live in Nevada. *Id.* at 8.

57. DNWest partners and collaborates with Nevada-based health institutions such as the University of Nevada (Reno School of Public Health), the Nevada Hospital Association, Donate Life Nevada, and other Nevada health and community-based organizations. *Id.* DNWest also established the Northern Nevada Advisory Council, which includes Northern Nevada community leaders and stakeholders who lead outreach efforts in their communities to create opportunities for people to understand the donation process and to consider registering to be organ donors. *Id.* at 7–8. DNWest's Chief Executive Officer sits on the Access to Healthcare Network Board of Directors, a Nevada organization that focuses on health-related outreach to underserved communities. *Id.*

58. DNWest has three dedicated full-time in-house coordinators who work at Renown and are in the facility every day, completing daily rounds in emergency and critical care units at Renown. *Id.* at 3, 23. These coordinators have developed deep and trusted relationships with Renown staff that continue through the present day, ensuring optimal communication and service.

59. DNWest has created other strategic commitments to ensure that that the partnership between DNWest and Renown remains strong and continues to result in high donor rates. For instance, DNWest spends a considerable amount of time inside Renown meeting with administrators and practitioners, providing education to staff, and participating in hospital committees. These efforts include bi-monthly meetings with Critical Care Nursing leadership; quarterly Donor Council meetings; quarterly C-suite meetings with the chief executive officer and chief nursing executive of Renown; year-round education for clinical staff; departmental meeting representation including in

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the Palliative, Trauma, Quality/Risk, Surgical Services, and Social Work departments; Donate Life Month activities to promote the state registry within the hospital; events designed to honor donors and their families that include Renown staff; and engagement at Intensivist monthly meetings for After Action Review with physician partners. *Id.* at 23.

60. Renown has renewed its affiliation agreement with DNWest every four years for the last forty years and never previously sought a waiver. Nor has it ever lodged a single complaint about DNWest's services at any of its facilities. On the contrary, even when sending a termination notice to DNWest following its waiver request, Renown's CEO Dr. Brian Erling stated that DNWest had done "great work" during its "many years of service" to "patients and families in critical need of organ donations." *Id.* at 3 n.2 (cleaned up).

61. DNWest's partnership with Renown is not only important because it has been exceptionally successful in its own right but also because it has sustained DNWest's efforts in the rest of its Northern Nevada donation service area. DNWest's donation service area includes both larger hospitals like Renown that can be anticipated to have a substantial number of donations each year but also smaller hospitals that may have only one or two donations a year but still need support.

62. Having Renown in its donation service area allows DNWest to benefit from economies of scale to serve all of its designated service area. DNWest may not be able to provide these smaller hospitals with the same high level of service without partnerships with larger hospitals like Renown.

C. Nevada Donor Network's Unlawful Scheme

63. Nevada Donor Network is an organ procurement organization based in Las Vegas, Nevada. It is designated under federal law to serve only those hospitals located in the Southern Nevada donation service area.

64. Nevada Donor Network's Las Vegas headquarters are located approximately 435 miles from the Northern Nevada donation service area, DNWest's Reno office, and Renown.

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65. While the leadership at Nevada Donor Network has changed since it was declared a "A Member Not in Good Standing," Nevada Donor Network continues to have performance statistics that raise serious concerns.

a. Nevada Donor Network has a consistently high kidney discard rate, meaning that a comparatively high percentage of the kidneys it recovers are not transplanted. High discard rates are not only wasteful financially, but also represent a serious disservice to donor families and a de-motivator to potential donors. Exhibit 3 at 20.

b. In 2022, Nevada Donor Network had the worst kidney discard rate among all organ procurement organizations nationally, with a kidney discard rate of 40.3%. *Id.* at 18. In comparison, DNWest's kidney discard rate is consistently low and nearly the best in the country. In 2022, its discard rate was 18.3%, well below the national average of 26.6%. *Id.* In fact, 42% of Nevada Donor Network hospitals (5 of 12) had a kidney discard rate of greater than 50% in 2022, while 0% of DNWest hospitals (0 of 72) had the same high discard rate.

c. Nevada Donor Network has unusually high costs and fees for recovery of donated organs, with the third highest kidney acquisition fee in the nation. *Id.* at 17. In 2022, DNWest's kidney Standard Acquisition Charge—the average of the total actual costs associated with procuring an organ—was 14.2% less than Nevada Donor Network's kidney standard acquisition charge. *Id.* As a result, every kidney procured with Nevada Donor Network ends up costing Medicare substantially more than a kidney procured by DNWest.

d. DNWest also has a higher donation rate in Nevada than Nevada Donor Network. *Id.* at 9–10; *see id.* at 11.

66. Beyond the performance metrics, there are significant concerns about the way Nevada Donor Network manages its existing relationships and its business more generally.

67. For instance, several commenters to CMS's rulemaking docket noted that Nevada Donor Network does not appear capable of managing a healthy relationship with the transplant center that exists in its own donation services area, University Medical Center in Las Vegas. In 2023, that transplant center completed only 15% of its transplants from Nevada Donor Network

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donors. In comparison, a local transplant center in DNWest's donation service area completed more than 40% of its transplants from DNWest donors.

68. In 2021, Nevada Donor Network's lavish spending on items caught the attention of the U.S. Congress House of Representatives Subcommittee on Economic and Consumer Policy, which subpoenaed Nevada Donor Network's records and launched a probe into the organization's spending practices. Exhibit 2 at 2; *see also* Letter from H. Comm. on Oversight & Reform, Subcomm. on Econ. & Consumer Pol'y, 117th Cong., to Joseph Ferreira, President & CEO, Nevada Donor Network ("House Committee Letter"), at 1-2 (May 27, 2021), https://tinyurl.com/yr8y459w. That spending included season NFL tickets, extravagant board retreats costing over $100,000 per year to destinations like Napa Valley, luxury gifts such as cases of wine and autographed memorabilia, and a $40,000 payment to a Forbes ghostwriter to write a book about Nevada Donor Network's business management strategies. Exhibit 2 at 2.

69. Executive compensation has also risen drastically at Nevada Donor Network. *See* House Committee Letter at 5 (executives at Nevada Donor Network are "highly compensated" and "taxpayers cover much of this executive compensation."). Compensation for the chief executive officer alone rose over 42% from 2018-2021 based on Nevada Donor Network's IRS Form 990s. Exhibit 2 at 1; *see also* House Committee Letter at 5 (noting that "taxpayers paid at least $517,000" of the $1,308,025 the chief executive officer of Nevada Donor Network received between 2017 and 2019).

70. Congress also has concerns about Nevada Donor Network's conflicts of interest with its for-profit businesses, including in the areas of tissue processing and laboratory services. *See* House Committee Letter at 6 (noting that the congressional testimony of Nevada Donor Network's CEO was misleading Congress noted that the "lack of forthrightness about [the organization's for-profit businesses] at the hearing raise concerns about conflicts of interest" for Nevada Donor Network "in carrying out [its] primary public mission to secure more organs for transplant." *Id*.

71. Instead of addressing these issues, Nevada Donor Network has focused on expansion, seeking to become the *only* organ procurement organization in Nevada. To that end, Nevada Donor

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Network developed and promoted a campaign intended to push DNWest out of its federally designated donation service area. The slogan of this campaign is "Take the North."

72. In service of this campaign, Nevada Donor Network has repeatedly made false statements suggesting that DNWest is not "Nevada-based" because it also serves California counties, Exhibit 3 at 11, or that switching from DNWest to Nevada Donor Network would mean that all organs recovered at Renown will stay in Nevada and be transplanted in Nevada—even though that representation is contrary to federal allocation policy. *Id.* at 16, Exhibit 5 at 3. Even if Nevada Donor Network were to become Renown's organ procurement organization, under current organ allocation policy, any organs recovered at Renown would still need to be allocated to transplant centers that remain in DNWest's service area, including the California counties. Exhibit 3 at 16.

73. Nevada Donor Network's primary action to achieve this business objective has been attempting to poach Renown through the waiver process and thereby disrupt DNWest's exceptionally successful partnership with Renown.

74. While the performance data does not show that donations would increase if Nevada Donor Network becomes Renown's organ procurement organization, that change would benefit Nevada Donor Network financially. Because Renown is the second largest donor hospital in Nevada, serving that hospital would allow Nevada Donor Network to quickly boost its own revenues and metrics without having to spend—as DNWest has—forty years investing in Renown, the Reno community, and the rest of the Northern Nevada service area. *Id.* at 14 (citing tbl.2, figs.7-9).

75. Nevada Donor Network's interference with DNWest's relationship with Renown began shortly after Nevada Donor Network was awarded $15 million in federal American Rescue Plan Act funds that were distributed throughout the State of Nevada. The funds granted to Nevada Donor Network were earmarked to support the creation of a transplant center in Nevada.

76. At some point before May 2023, Nevada Donor Network made an offer to Renown to build a transplant center—the Nevada Transplant Institute —in Reno. Nevada Donor Network conditioned this offer on Renown requesting a waiver from CMS to change its organ procurement organization to Nevada Donor Network.

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77. The transplant center would be operated by Renown and partially under the control of Nevada Donor Network, contrary to federal and state law and policy, which require strict separation between organizations that recover organs and those that receive them for transplant.

78. At a meeting in May 2023, Renown's chief executive officer Dr. Brian Erling informed the chief executive officer of DNWest at a public meeting that Renown was in dire financial straits and Nevada Donor Network had offered to provide Renown millions of dollars in initial funding to build a transplant center at Renown if Renown would submit a waiver request to CMS in favor of Nevada Donor Network. *Id.* at 25–26, Exhibit 5 at 2.

79. At that meeting, Dr. Erling asked whether DNWest could provide any financial resources to Renown, but DNWest's chief executive officer explained that, as an organ procurement organization, it could not lawfully provide any funding to create a transplant center.

80. On June 21, 2023, unbeknownst to DNWest at the time, Nevada Donor Network and Renown entered into a memorandum of understanding. In this memorandum of understanding, Nevada Donor Network pledged $6 million dollars in initial funding to Renown for construction expenses, salaries, and other operating expenses. In addition, Nevada Donor Network committed to securing an additional $9 million in support of the transport program and the "sharing of resources" including "staff" and "laboratory services" to support the transplant program.

81. Shortly afterwards, at a public meeting in August, Renown publicly advocated for Nevada Donor Network to become its organ procurement organization, and it submitted its request to CMS for a waiver on September 11, 2023. Exhibit 6 (Waiver Request).

82. Renown's waiver request encompassed three hospitals it operates in the Reno area:

- Renown Regional Medical Center, Provider No. 29-0001;
- Renown South Meadows Medical Center ("Renown South"), Provider No. 29-0049; and
- Renown South Meadows Medical Center d/b/a Renown Rehabilitation Hospital ("Renown Rehab"), Provider No. 29-0049.

83. Renown's application for waiver made no mention of the monetary incentive that Nevada Donor Network had improperly offered. Instead, Renown's request suggested that a switch

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to Nevada Donor Network would "increase organ donations" because (a) Nevada Donor Network was Tier 1 as of April 2023, (b) Nevada Donor Network covered eighty percent of the state's population (fourteen of seventeen counties in Nevada), and (c) Nevada Donor Network's offices were purportedly close to Renown. *Id.* at 1–2. The waiver request asserted that Nevada Donor Network would ensure equitable treatment of patients because Nevada Donor Network would follow "all national allocation policies set forth by the OPTN." *Id.* at 3.

84. Shortly after Renown submitted its waiver application but before CMS granted the waiver, Renown sent a termination letter to DNWest stating that it would be unilaterally cancelling its federally mandated Affiliation Agreement with DNWest without cause, effective January 4, 2024. (As noted below, Renown later changed this demand, and the agreement is now scheduled to terminate on March 31, 2025, absent relief from this Court.)

85. While the waiver request remained pending, DNWest brought suit against Nevada Donor Network for its unlawful conduct. As alleged in the lawsuit, Nevada Donor Network's offer of up to $15 million to Renown to contribute to the building of Renown's Nevada Transplant Institute in exchange for Renown applying for a waiver violates the federal and Nevada anti-kickback statutes and in so doing, violates Nevada deceptive and unfair trade practices laws. That lawsuit is ongoing, and in September 2024, the Court denied Nevada Donor Network's motion to dismiss with respect to DNWest's claims for intentional interference with contractual relations, intentional interference with prospective economic advantage, violations of the Nevada Deceptive Trade Practices Act, and its request for punitive damages.

86. Renown has continued to work with DNWest throughout the waiver process and litigation. That working relationship, while tested by Nevada Donor Network's unlawful conduct, remains strong, and the relationships that DNWest has spent decades developing will hold as long as it is able to continuously maintain its work for Renown's hospitals. Performance metrics have not suffered as a result of the waiver process or related litigation.

87. Pursuant to Renown's Affiliation Agreement with DNWest, after having its waiver granted, Renown will continue to work with DNWest until 90 days after giving notice of the waiver

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(for organ donation). On December 24, 2024, Renown notified DNWest that the waiver would take effect on March 31, 2025.

D. CMS's Approval of Renown's Waiver Request

88. Following Renown's submission of its request for waiver, CMS published three separate notices for each of Renown's hospitals in the Federal Register on November 24, 2023. 88 Fed. Reg. 82,375 (Nov. 24, 2023) (Renown Medical); 88 Fed. Reg. 82,381(Nov. 24, 2023) (Renown South d/b/a Renown Rehab).

89. The public comment period for the waiver request ended on January 23, 2024.

90. Renown's waiver request received 168 comments, 89 of which were unique comments.

91. Commenters opposing the waiver request raised significant and serious objections that approving such request would reduce donations, harm patients, and undermine the statutory requirements.

92. Despite the record evidence presented to CMS—hundreds of pages of comments, including detailed data analyses and figures—the CMS approved the waiver request on December 19, 2024. The substance of CMS's decision is limited to four short paragraphs that, in a conclusory fashion, assert that "granting the waiver is expected to increase organ donation and will ensure equitable treatment of patients referred for transplants within the service areas served by Donor Network West and Nevada Donor Network." Exhibit 1 at 1.

1. Granting the Waiver Request Will Not Increase Donation Rates

93. CMS has no authority to grant a waiver request unless the waiver is "expected to increase organ donation." 42 U.S.C. § 1320b-8(a)(2)(A), (B); *see also* 42 CFR § 486.308(e).

94. Renown's waiver request failed to present *any* evidence that granting the waiver would increase donation rates. Moreover, although numerous comments presented evidence that granting the waiver would decrease donation rates and undermine the statutory requirements, CMS never meaningfully addressed these comments.

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95. *First*, the waiver request stated that donation rates would increase because Nevada Donor Network is Tier 1: "[Nevada Donor Network] is a Tier 1 [organ procurement organization] …. Based on this independently reported data, we are confident [Nevada Donor Network] will assist Renown to 'increase organ donations' in the hospital system as a result of our Agreement." Exhibit 6 at 2 (emphasis omitted).

96. In response, commenters submitted evidence indicating that DNWest outperforms Nevada Donor Network in the State. Exhibit 3 at 9; *see also id.* at 10 ("RRMC's waiver request is not predicated upon NDN or RRMC working together to increase a poor organ donation recovery rate; RRMC, thus Washoe County, already has *extremely high* organ donation rates due to the partnership between DNWEST and RRMC, as shown through *the CMS calculations using the new performance metrics*." (emphasis added)).

97. Commenters in "strong opposition" to the waiver request presented verifiable data indicating that granting the waiver request would *not* increase the amount of donations despite Nevada Donor Network being deemed Tier 1. Exhibit 2 at 1 (emphasis omitted) (analyzing SRTR Organ Utilization Data that indicates "**NDN ranks 55/56 (the 2nd LEAST efficient)** at successfully getting procured kidneys transplanted to patients. This is in stark comparison with **DNW, that ranks 6/56 (6th MOST efficient) with only 20.9% of their Kidneys recovered for Transplant not getting transplanted**" (emphasis in original)); Exhibit 7 at 1 ("In 2023, the local Las Vegas transplant center completed 17% (2) of their transplants from Nevada Donor Network donors — this is not the standard dynamic for an [organ procurement organization] and their local transplant center.").

98. CMS did not address these comments and concerns. Instead, CMS merely asserted, without analysis, that a higher (interim) tier ranking necessarily means "donation rates are expected to increase." Exhibit 1 at 3. CMS cited the 2023 OPO Public Performance Report (the "2023 Report") that denotes DNWest as Tier 2 and Nevada Donor Network as Tier 1. Exhibit 1 at 2. But the 2023 Report is a snapshot in time—it reflects *only* data from calendar year ("CY") 2021—of a four-year recertification cycle by which the final tier determination will be made in 2026. *See* Annual Public Aggregated Performance Report, https://tinyurl.com/2k4bywvp.

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99. The tiering system was never intended to be used to determine whether a waiver would increase donations and make more equitable the treatment of patients for a *specific* hospital. It is not one of the statutory or regulatory factors CMS is permitted to consider (e.g., cost effectiveness, improvements in quality, and length and continuity of the hospital's relationship with the designated organ procurement organization.). The tiering system is instead designed to answer a different question: how has the organization performed in its *entire donation service area* over the course of a four-year period for purposes of recertification.

100. The tiering system is contrary to the standards that must be applied when considering waiver requests—i.e., to continue to ensure effective coverage of each donation service area—and commenters raised to CMS that the tiering system created a competitive environment where organ procurement organizations "must now compete with each other in order to maintain their certification and their [donation service area]" and could possibly "woo hospitals from 'competitor' [organization] in attempt to gain a competitive advantage and create instability." Exhibit 8 at 1.

101. *Second*, the waiver request stated that because Nevada Donor Network covered fourteen of the seventeen counties in Nevada, that fact would "be an additional factor contributing to the success of this new relationship." Exhibit 6 at 1. According to Renown's waiver request, "[t]he infrastructure of [Nevada Donor Network] and location of its offices in proximity to Renown also allows for more cost-effective coverage and service to our hospital and community." *Id.* at 1–2.

102. Commenters pointed out that Renown's claim was misleading. Although Nevada Donor Network is designated for fourteen counties in Nevada, it *serves* only seven counties with a hospital. Moreover, Nevada Donor Network serves only "a single transplant center"—the University Medical Center of Southern Nevada in Las Vegas. Exhibit 3 at 15.

103. Northern Nevada patients are closer to DNWest transplant centers than to the Las Vegas transplant center "by nearly half the distance." *Id.* at 16 (emphasis omitted). In fact, "Las Vegas is located two times farther from [Renown] than is [DNWest]'s … San Francisco/San Ramon" transplant centers. *Id.* at 17. DNWest "has a solid brick-and-mortar Northern Nevada office building one mile from Renown and has an actual DNWest office in [Renown] itself." *Id.* DNWest's

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northern Nevada team consists of over forty employees, "including three In-House Coordinators devoted strictly to the Renown donation program and are on-site 7 days a week." Exhibit 9 at 1. Many of the other forty employees provide routine service at Renown.

104. It should not have been difficult for CMS to confirm this important information. Instead, the CMS's decision categorized both Renown's and the comments against the waiver's positions as "competing claims" where neither DNWest or Nevada Donor Network had "a clear advantage over the other in terms of geographical location that might translate into increased quality or cost effectiveness." Exhibit 1 at 2–3.

105. *Third*, Renown's waiver request cited data in support of granting a waiver using the "Donors per Million" metric. This calculation "has not been used for at least two decades by CMS and is not used in the industry at all due to its crude measurement of OPO performance." Exhibit 3 at 12; *see also* 71 Fed. Reg. 30,982, 30,985 (May 31, 2006) (explaining that CMS was shifting away from the donors per million population metric to organ donor potential because "it will be a more accurate measure of the donor potential in a [donation service area]."). Even still, commenters presented CMS with data using the obsolete metric that illustrated that "DNWest outperforms [Nevada Donor Network] …." Exhibit 3 at 12.

106. CMS "acknowledge[d]" DNWest's "awards and recognitions" but fell back on the tiering system as the main driver for granting the waiver request. Exhibit 1 at 3.

2. Granting the Waiver Request Will Not Ensure Equitable Treatment

107. CMS may grant a waiver only if it determines that it "will assure equitable treatment of patients referred for transplants within the service area served by such hospital's designated organ procurement [organization] and within the service area served by the organ procurement [organization] with which the hospital seeks to enter into an agreement under the waiver." 42 U.S.C. § 1320b-8(a)(2)(A), (B); *see also* 42 CFR § 486.308(e).

108. Renown's waiver request failed to present *any* evidence that granting a waiver would ensure equitable treatment for patients awaiting transplant in the DNWest donation service area.

109. The waiver request suggested only that because Nevada Donor Network would be required to follow all relevant policies set forth by the Organ Network—policies that all organ

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procure organizations must follow—Nevada Donor Network's compliance would *per se* meet the equitable treatment requirement.

110. Organ Network policies "are rules that govern operation of *all* member transplant hospitals, [and] *organ procurement organizations* …." HRSA, Organ Procurement & Transplantation Network, *Policies: OPTN Policy* (Mar. 5, 2025), https://tinyurl.com/4c2a33cb (emphasis added). In other words, *all* member transplant hospitals must ensure equitable treatment in order to comply with Organ Network policies.

111. Several comments highlighted the operational inefficiencies that would result from the waiver. For example, a former Nevada Donor Network employee commented and explained:

> NDN will not provide service levels on par with DNW. NDN's high kidney discard rate supports this assertion (40.3% in 2022) compared to DNW's lower rate (17.5% in 2022), against a national average of 26.6%. The expansion of NDN's donation service area (DSA), 430 miles away from its main office in Las Vegas, would strain resources, diminish service quality in their current and expanded areas, and ultimately [would be] counterproductive to their mission of serving the Nevada community.

Exhibit 10 at 1; *see also* Exhibit 3 at 16 ("If the waiver is granted, alignment, logistics, and unnecessary greater distance will become more complicated and difficult, not to mention the increased cost and lower quality."); Exhibit 10 at 2; Exhibit 3 at 18–19 (referencing numerous figures, including identifying Nevada Donor Network as having the highest discard rate in the nation).

112. CMS failed to address the realities of non-compliance with the Organ Network rules (as evidenced in the comments), assuming that granting the waiver would not "impact the regional distribution of organs in the service area" because "national organ allocation policies set forth by the OPTN will help ensure equitable treatment of patients referred for transplants in both service areas." Exhibit 1 at 3. CMS provided no support for this position, nor does the final decision address comments that provided evidence to the contrary.

113. CMS instead relied again on the tiering system, asserting that because Nevada Donor Network was Tier 1, its "rating will both improve and ensure the equitable treatment of patients" with no further evidence or support. *Id.* at 3.

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3. All Other Factors Weigh Against Granting the Waiver Request

114. CMS may also consider certain factors when reviewing waiver requests, including cost effectiveness, quality improvements, and "the length and continuity of a hospital's relationship with an [organ procurement organization] other than the hospital's designated [organ procurement organization]." 42 U.S.C. § 1320b-8(a)(2)(A), (B); *see also* 42 CFR § 486.308(e).

115. CMS's decision concluded that neither DNWest nor Nevada Donor Network had an advantage over the other in terms of cost effectiveness or quality improvements: "With respect to geographical location, both Donor Network West and Nevada Donor Network claim to have headquarters or office locations that are geographically advantageous to Renown Health. In light of these competing claims, CMS does not consider either … to have a clear advantage …." Exhibit 1 at 2–3. But, as noted above, that was incorrect and not supported by any record evidence.

116. Commenters also strongly disagreed generally on the notion that the waiver would be cost effective, informing CMS that the waiver "will likely increase transplant hospital costs, private insurance costs, patient expenses, and CMS expenses …." Exhibit 2 at 1. For example, Nevada Donor Network's acquisition fee is the third highest in the nation. Exhibit 3 at 17. Moreover, DNWest's kidney standard acquisition charge is 14.2% ($56,900) less than Nevada Donor Network's kidney standard acquisition charge ($65,000) and "[t]he cost to Medicare and taxpayers may actually be many times greater than the cost of just the increased [standard acquisition charge] because it is compounded by the exorbitant NDN kidney discard rate of 40.3% … the highest in the nation amongst the [55] OPOs, 52% greater than the NATIONAL average kidney discard rate (26.6%) and over TWICE (120% greater than) DNWest NEVADA's kidney discard rate (18.3%)." *Id.* at 18; *see also* Exhibit 11 at 1 (explaining that because Nevada Donor Network has the highest discard rate in the country, "there is inadequate justification for granting the waiver. In fact, the waiver may have the opposite effect by increasing cost and causing fewer organs to be place.").

117. CMS did not reference the information and data presented in the comments. CMS's decision did recognize that the switch to Nevada Donor Network could be more costly, but CMS merely asserted that it did "not believe that any potential increase would outweigh … other considerations," e.g., the tiering system. Exhibit 1 at 3.

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118. CMS also indicated that the relationship between Renown and DNWest had deteriorated since "[DNWest's] lawsuit against Renown Health and related public statements, which Renown Health contends mischaracterized its intent in seeking to change [organ procurement organizations]." *Id.* at 2. But CMS provided no context for that conclusion. Nor did the agency address or provide any reasoned explanation for addressing the evidence that Renown requested the waiver for financial reasons.

119. Granting a waiver that is requested based on monetary consideration raises profound legal and ethical issues. Organ procurement organizations are non-profit recipients of federal dollars and should not offer financial consideration for access to potential donors.

120. Public perception of real or perceived shady practices can have a serious impact on public trust in the sacred mission of organ donation. Exhibit 8 at 1. As commenters noted, "the alleged financial offers from [Nevada Donor Network] … could seriously undermine the ethical integrity of this life-saving mission" and "[t]he potential impact on donor confidence must be considered; trust is paramount in encouraging donor participation." Exhibit 10 at 1. As another commenter noted, "No waiver should be granted until a thorough investigation evaluates the use of taxpayer dollars to bribe a hospital system." Exhibit 12 at 1.

121. Granting a waiver under these circumstances would set a dangerous precedent. Organ procurement organizations with performance problems would be incentivized to boost their metrics by poaching the most successful hospital systems from neighboring service areas—all without having to go through the more rigorous process of applying for the service area and without investing in smaller hospitals or more rural areas in the service area. Exhibit 8 at 1. As one commenter noted, "this process could be used strategically by [organ procurement organizations] to woo hospitals from 'competitor' [organizations] in an attempt to gain competitive advantage and create instability" even though that would "disrupt[] … delicate and hard-earned relationships" between the hospital and its designated [organ procurement organization]. *Id.* Yet CMS failed to address any of these comments.

122. Nor did CMS address numerous other concerns and objections that were raised, including (1) a congressional request for documents following a hearing where the chief executive officer of Nevada Donor Network confirmed that Nevada Donor Network holds season tickets for

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the National Football League's Las Vegas Raiders and the National Hockey League's Las Vegas Golden Knights and spent money on multiple board retreats to California wine country, Exhibit 2 at 2, Exhibit 13 at 1; (2) Nevada Donor Network was the first and is one of the only organ procurement organizations to be named "A Member Not in Good Standing" by the Organ Network/UNOS governing board due to repeated failures, Exhibit 2 at 3, Exhibit 13 at 2; (3) Nevada Donor Network had lost Eye Bank Association of America accreditation, Exhibit 2 at 3; and (4) Nevada Donor Network refused to collaborate with its local transport center in Las Vegas, Exhibit 7 at 1, Exhibit 14 at 1 (explaining that Nevada Donor Network "doesn't seem capable of managing a healthy relationship with the only transplant center that exists right in their own [donation service area]").

BASIS FOR EMERGENCY INJUNCTIVE RELIEF

123. DNWest faces a substantial threat of irreparable injury if the waiver is not set aside before it takes effect—on March 31, 2025 for organ donation.

124. Irreparable harm includes damage to reputation, goodwill, and ongoing recruitment efforts. *See Rent-A-Ctr., Inc. v. Canyon Television & Appliance Rental, Inc.*, 944 F.2d 597, 603 (9th Cir. 1991). DNWest has spent forty years building and maintaining relationships with hospitals, medical providers, service contractors, and the community in northern Nevada. Success within the organ and tissue donation community is built upon these relationships, and DNWest's partnership with Renown has been extremely successful, with Renown becoming one of the top hospitals for organ donation recovery in the entire country.

125. If the waiver is permitted to take effect, DNWest will be forced to cease its operations at Renown. As it stands, DNWest continues to work in Renown at a daily basis, maintaining positive relationships with hospital staff and physicians and continuing to execute its long-term programs and strategic projects.

126. Once the waiver takes effect, DNWest will be forced to leave Renown, disrupting relationships DNWest has spent forty years developing. The three in-house coordinators will leave the hospital and all ongoing collaborative projects, outreach efforts, and programs will come to an abrupt stop, jeopardizing the success of long-term initiatives.

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127. Irreparable injury will occur if DNWest is forced to cease its operation at Renown. To leave and come back will require rebuilding relationships and slowly rebuilding the trust of those who work at Renown. It is likely that confusion around the switch will be attributed to DNWest, resulting in further reputational damage.

128. If the waiver takes effect, it will also irreparably tarnish the reputation of DNWest in the Reno community and its northern Nevada donation service area at large. The waiver obscures (or even blesses) the monetary motivation Renown had for seeking the waiver and suggests—despite the absence of complaints and DNWest's proven track record—that Renown was not properly served by DNWest.

129. DNWest has received reports from its community partners confirming reputational damage. If the waiver is not set aside, and DNWest is required to leave Renown, this reputation damage may, in turn, motivate other hospitals to seek to terminate their relationships with DNWest.

130. If the waiver decision is not enjoined and the status quo is not maintained, DNWest's ability to serve the rest of its donation service area will become more challenging, as some established programs at other hospitals rely on economies of scale. DNWest will lose relationships and goodwill with volunteers, providers, and community partners at Renown and at other area hospitals.

131. If the waiver is permitted to stand, it will also have broader negative impacts on organ donation that disserve the public interest.

132. Federal law created donation service areas in order to maximize the efficiency of the organ donation network. If Nevada Donor Network is permitted to get away with poaching Renown via waiver after openly providing a monetary *quid pro quo* to induce Renown to seek the waiver, this conduct will become more commonplace for DNWest's hospital partners and around the country. Organizations willing to pay large sums of money will be able to game the tiering system by poaching high-performing hospitals from neighboring OPOs to improve their metrics and revenues. Multiple organ procurement organizations (other than DNWest) submitted comments to the agency detailing this concern and the negative impact such conduct could have on organ donation

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across the country. A waiver should not be used as a workaround for the requirement to compete for entire service areas at a time.

133. Granting the waiver under these circumstances is especially concerning given CMS's new tiering rule, which ranks organ procurement organizations comparatively and then decertifies and eliminates the ability for the third tier to continue to compete for donation service areas. The incentives for an organization to poach high-performing hospitals to boost its own metrics (and simultaneously hurt a neighboring organization's metrics) will be high during this period of zero-sum competition.

134. Furthermore, tiering data from year-to-year is highly variable. If a hospital is able to obtain a waiver simply on grounds that another organ procurement organization was ranked at a higher Tier during a particular year than its current organ procurement organization, the nation's service area system will be destabilized. Many hospitals may become up for grabs at once and one hospital could even seek multiple waivers within a relatively short amount of time, leading to unstable boundaries of service areas and unstable relationships within them.

135. Human lives depend on the organ donation network working effectively. If the public does not believe that the entities that control organ procurement and transplantation are honest and follow federal requirements, fewer individuals will agree to provide this life-saving gift.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Agency Action in Excess of Statutory Authority
CMS Failed to Make the Determinations Necessary to Support the Statutory Criteria for Granting a Waiver

136. DNWest incorporates and realleges Paragraphs 1 through 135 above as if fully set forth herein.

137. Under the Administrative Procedure Act, a reviewing court must "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(A), (C).

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138. Congress has authorized the Secretary to grant a waiver only if the Secretary affirmatively determines that "the waiver is expected to increase organ donation" and "the waiver will assure equitable treatment of patients referred for transplants within the service area served by such hospital's designated organ procurement agency and within the service area served by the organ procurement agency with which the hospital seeks to enter into an agreement under the waiver." 42 U.S.C. § 1320b-8(a)(2)(A).

139. Instead of making these required determinations, the Secretary used an interim tier rating as a proxy for both the statutory requirements and without making any factual findings that would be necessary to determine whether a tier rating could serve as an appropriate proxy.

140. Tiering data cannot serve as a proxy for the first statutory criterion because it covers an organization's performance on a donation service area wide basis, whereas the waiver criterion looks only to whether a waiver will increase the donation rate at a specific hospital. The tier status of an organ procurement organization based on its existing donation service areas has no bearing on the second statutory criterion. The statute's "equitable treatment" requirement looks to whether granting the waiver—that is, affirmatively altering the bounds of each service area—will ensure equitable treatment of patients on the transplant list within *both* organization's donation service areas. Making a decision based solely on pre-waiver tier status does not answer this requirement, as it does not examine how the change will impact the treatment of patients within both donation service areas, including the one left behind.

141. Moreover, the tiering data available to CMS at the time it issued its waiver decision was solely in the form of highly variable interim performance reports, none of which will be used to determine the final tier status of any organ procurement organization for the 2026 certification cycle.

142. By failing to make the determinations that Congress deemed necessary to justify the grant of a waiver, the agency exceeded its statutory authority and its decision violates the statute.

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SECOND CLAIM FOR RELIEF

Violation of the Administrative Procedure Act
The Secretary Failed to Consider Compelling and Serious Allegations of Nevada Donor Network's Unethical and Unlawful Conduct

143. DNWest incorporates and realleges Paragraphs 1 through 142 above as if fully set forth herein.

144. Agency action is arbitrary and capricious of the agency fails to "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)).

145. An agency decision is arbitrary and capricious if the agency "(1) relied on a factor that Congress did not intend it to consider; (2) failed to consider an important factor or aspect of the problem; (3) failed to articulate a rational connection between the facts found and the conclusions made; (4) supported the decision with a rationale that runs counter to the evidence or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise; or (5) made a clear error in judgment." *Cal. Energy Comm'n v. Dep't of Energy*, 585 F.3d 1143, 1150–51 (9th Cir. 2009).

146. Failing to respond to significant comments is arbitrary and capricious. *See Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015) ("An agency must consider and respond to significant comments received during the period for public comment."); *Lilliputian Sys., Inc. v. Pipeline & Hazardous Materials Safety Admin.*, 741 F.3d 1309, 1312 (D.C. Cir. 2014) ("An agency's failure to respond to relevant and significant public comments generally 'demonstrates that the agency's decision was not based on a consideration of the relevant factors.'" (quoting *Thompson v. Clark*, 741 F.2d 401, 409 (D.C. Cir. 1984))). "[S]ignificant comments" are "those which raise relevant points and which, if adopted, would require a change in the agency's" action. *Am. Mining Cong. v. EPA*, 965 F.2d 759, 771 (9th Cir. 1992) (quotation marks omitted).

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147. The Secretary's waiver decision is arbitrary and capricious because the agency failed to address significant comments and objections, including the important and serious allegations that Nevada Donor Network procured the waiver request through illegal and unethical conduct.

148. Renown submitted the waiver because it was induced by the offer of millions of dollars to build a transplant center, which Nevada Donor Network unlawfully conditioned on Renown submitting a waiver to switch organ procurement organizations. Such conduct by Nevada Donor Network violates federal and state law, as well as constituting unlawful business practices under Nevada law. Moreover, Nevada Donor Network's ownership interest in the transplant center constitutes a profound conflict of interest with its obligation to equitably allocate the organs it recovers to transplant centers without financial incentive to prioritize any particular center over others.

149. The Secretary failed to address these allegations, instead mentioning the lawsuit only in passing to suggest that it negatively impacted DNWest's working relationship at Renown (without citing evidence that there has been any actual impact on performance metrics).

150. The Secretary also failed to consider or address significant record evidence, including the congressional inquiry into lavish spending at Nevada Donor Network, the congressional inquiry into conflicts of interest with its for-profit businesses, and concerns commenters raised about Nevada Donor Network's inability to manage a productive relationship with the transplant center in its own donation service area.

151. Because the Secretary did not address the allegations that the waiver was a product of improper and illegal conduct, the agency failed to address the comments asserting that granting a waiver before these allegations are resolved threatens to diminish public trust in organ donation.

152. The Secretary likewise failed to mention or meaningfully address comments raising serious objections that allowing a waiver would have devastating system-wide effects on the organ donation network, as other organ procurement organizations would be incentivized to boost their revenues and (at least temporarily) boost their performance metrics by cherry-picking the largest donor hospitals from neighboring organization' donation service areas.

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153. The Secretary swept aside and failed to respond to comments establishing that DNWest has forty years of proven success at Renown, higher performance statistics within Nevada service areas than Nevada Donor Network, significantly lower costs associated with organ procurement, a lower kidney discard rate, and geographic advantage.

154. The agency also failed to consider how the loss of Renown would impact DNWest's ability to serve its other hospital partners with the donation service area or sustain to the same degree its continued investments in the northern Nevada community.

155. The Secretary's grant of the waiver is arbitrary and capricious and must be set aside.

THIRD CLAIM FOR RELIEF

Violation of the Administrative Procedure Act
The Secretary Failed to Articulate a Rational Connection Between the Facts Found and the Conclusions Made

156. DNWest incorporates and realleges Paragraphs 1 through 155 above as if fully set forth herein.

157. In deciding whether an agency violated the arbitrary and capricious standard, the court must ask whether the agency "articulated a rational connection between the facts found and the choice made." *Ariz. Cattle Growers' Ass'n v. U.S. Fish & Wildlife*, 273 F.3d 1229, 1236 (9th Cir. 2001); *see also State Farm*, 463 U.S. at 42–43, 52 (an agency must act in a way that is "rational," "reasonably explained," and "based on a consideration of the relevant factors." (quotation marks omitted)).

158. The Secretary's decision relies on irrational and illogical reasoning. The agency predicated its decision on tier status but tier status does not comply with the statutory requirements.

159. The Secretary was irrational with respect to considering the pending lawsuit concerning Nevada Donor Network's unlawful conduct. The agency considered only the potential negative impact such a lawsuit could have on DNWest's relationship with Renown and failed to take any notice of the serious underlying allegations. There was no evidence that the litigation had negatively impacted DNWest's performance metrics at Renown. But even if there had been,

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granting the waiver (and thereby rewarding the unlawful instigator of the conflict) is an irrational response.

160. The Secretary's assertions about the "equitable treatment" statutory requirement suffered an additional flaw. The agency concluded that because Nevada Donor Network would be required to follow all relevant policies set forth by the Organ Network—policies that all organ procurement organizations must follow—Nevada Donor Network's compliance would *per se* meet the equitable treatment requirement. But that renders this statutory requirement meaningless. If all organ procurement organizations meet this requirement because they follow Organ Network policies, the statutory consideration would never weigh in any waiver decision.

161. For these reasons too, the Secretary's grant of the waiver is therefore arbitrary and capricious and must be set aside.

FOURTH CLAIM FOR RELIEF

Violation of the Administrative Procedure Act
The Secretary's Findings Run Counter to the Evidence
and Reflects a Clear Error in Judgment

162. DNWest incorporates and realleges Paragraphs 1 through 161 above as if fully set forth herein.

163. An agency decision is arbitrary and capricious if the agency "supported the decision with a rationale that runs counter to the evidence or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise" or if the agency "made a clear error in judgment." *Cal. Energy Comm'n*, 585 F.3d at 1150–51.

164. The Secretary's conclusions are contrary to all the evidence before the agency that was relevant to the statutory criteria.

165. There is no credible evidence that granting the waiver will increase organ donation. DNWest's performance with Renown has been unquestionably successful, with organ donation volume at Renown in the top one percent of all donor hospitals nationwide. Moreover, DNWest's performance in Nevada far outshines Nevada Donor Network's performance in Nevada. DNWest

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has a higher donation rate in Nevada than Nevada Donor Network. DNWest also has a far lower kidney discard rate and its costs for procuring an organ are less than Nevada Donor Network's costs.

166. Nor is there any evidence that the waiver will ensure equitable treatment of patients on the transplant list in both service areas. Commenters raised a host of equitable considerations regarding Nevada Donor Network's unethical behavior, conflicts of interest, excessive spending, and troubled relationship with its own transplant center.

167. As to the additional statutory considerations, cost-effectiveness plainly favors DNWest. Commenters presented evidence that Nevada Donor Network has the third highest kidney acquisition fee in the nation, and that DNWest's kidney standard acquisition charge is 14.2% lower than Nevada Donor Network's. Commenters also noted that the cost to Medicare and taxpayers may actually be many times greater than the cost of just the increased acquisition charge because it is compounded by the exorbitant Nevada Donor Network kidney discard rate of 40.3%, the worst kidney discard rate in the nation.

168. As to the "length and continuity" of a hospital's relationship with the organ procurement organization other than the hospital's designated organ procurement organization, there was no evidence to favor Nevada Donor Network. On the contrary, DNWest has had forty years of successful partnership whereas Nevada Donor Network only came into Renown's orbit when it unlawfully offered the hospital millions of dollars to switch organ procurement organizations. Even then, Renown tried to see whether DNWest could offer it commensurate funding instead of Nevada Donor Network before accepting Nevada Donor Network's offer.

169. As to improvements in quality, even though Renown is already one of the top donor hospitals in the country, commenters noted that in the last five years, DNWest helped Renown sustain a 46% increase over its already laudable donation rate in prior years. Exhibit 3 at 7.

170. For these reasons too, the Secretary's grant of the waiver is arbitrary and capricious and should be set aside.

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REQUEST FOR RELIEF

Donor Network West respectfully requests that the Court enter judgment in its favor and grant the following relief:

1. Preliminarily enjoin the implementation and/or enforcement of the waiver decision;
2. Issue an order vacating the waiver decision as invalid;
3. Enjoin implementation and/or enforcement of the waiver decision;
4. Award Plaintiff legal fees and the costs of suit as appropriate; and
5. Grant such other and further relief as the Court deems just and proper.

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Dated: March 7, 2025

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